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10/602,113

06/23/2003

Eugene F. Young

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11/13/2006

MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
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FOSTER CITY, CA 94404

EXAMINER

HYUN, PAUL SANG HWA

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/602,113 | | YOUNG ET AL. | |
| | Examiner | | Art Unit | |
| | Paul S. Hyun | | 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-26, 38-42 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

REMARKS

Claims 1-42 and 46 are pending. Claims 1-18 and 27-37 have been withdrawn as being drawn to non-elected inventions. Applicants also cancelled claims 43-45. Claims 19, 22 and 39 were amended.

The amendments to the claims overcome the claim objections cited in the previous Office action. Consequently, the objections have been withdrawn.

The amendments to the claims overcome the claim rejections under 35 U.S.C. 112 2nd paragraph cited in the previous Office action. Consequently, the rejections have been withdrawn.

The art rejections cited in the previous Office action are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **19-21, 23, 25, 26 and 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Henry (US 4,956,150) in view of Sha et al. (US 2003/0235519 A1).

Henry discloses a stick of microtiter wells (see Fig. 6). The stick comprises a substrate 25 having a plurality of sample chambers 36 formed thereon. Each well is in the form of a truncated hemisphere, the bottom of which comprises a plano-concave

lens surface (26') for focusing light that is transmitted through the well, wherein the bottom of the lens is planar and the top of the lens is concave.

The Henry reference differs from the claimed invention in that the wells of the microtiter stick disclosed by Henry are open and therefore they are not chambers. Moreover, the microtiter stick disclosed by Henry comprises only a single row of wells, not a matrix of wells.

In regards to the chambers, Sha et al. disclose a flat cover adapted to seal the wells of a microtiter plate (see Fig. 4B). The reference discloses that the cover can be made from a transparent polypropylene (see [0027]).

In light of the teachings of Sha et al., it would have been obvious to one of ordinary skill in the art to provide a transparent polypropylene cover to the wells of the microtiter stick disclosed by Henry in order to prevent sample contamination. The cover and the sample wells would form chambers.

In regards to providing a matrix of wells, microtiter plates comprising a matrix of wells, such as 9x12 or 16x24 matrix configuration, are well-known in the art. It would have been obvious to one of ordinary skill in the art to provide a matrix of wells to the microtiter stick so that it can accommodate more samples.

Claims **22 and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Henry in view of Sha et al. as applied to claims 19-21, 23, 25, 26 and 46, and further in view of Ohta et al. (US 5,169,601).

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Neither Henry nor Sha et al. disclose that the lenses disposed in the wells are convex lenses.

Ohta et al. disclose an optical system that focuses light transmitted through wells of a microtiter plate onto a CCD sensor. The system comprises a light source for transmitting light through a sample stored in the wells of the microtiter plate, and a convex lens that converges the transmitted light onto a CCD sensor that is positioned one focal length away from the convex lens (see Fig. 12 and lines 11-41, col. 9).

In light of the teachings of Ohta et al., it would have been obvious to one of ordinary skill in the art to replace the lens disclosed by Henry with a convex lens since convex lenses are specifically adapted to focus light at a distance of one focal length away from the lens.

Claim **24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Henry in view of Sha et al. as applied to claims 19-21, 23, 25, 26 and 46, and further in view of Warhurst et al. (US 6,896,848 B1).

Neither Henry nor Sha et al. disclose a metallic member.

Warhurst et al. disclose a flat cover adapted to seal the wells of a microtiter plate (see Fig. 1). The reference discloses that the cover can be made from a metal (see lines 65-67, col. 2).

In light of the teachings of Warhurst et al., it would have been obvious to one of ordinary skill in the art to provide a metallic cover to the wells of the microtiter stick

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disclosed by Henry in order to prevent sample contamination while the samples are not being analyzed.

Claim **39** is rejected under 35 U.S.C. 103(a) as being unpatentable over Henry in view of Sha et al. as applied to claims 19-21, 23, 25, 26 and 46, and further in view of Masahiko (EP Application 0065409 A2).

Neither Henry nor Sha et al. disclose that the lenses disposed in the wells are Fresnel lenses.

Masahiko discloses an optical system adapted for analyzing agglutination patterns of samples disposed in a microplate. The system comprises a light source 3 for projecting light onto the samples and a Fresnel lens 6 for focusing the light onto the wells of the microtiter plate (see Fig. 1 and pages 7-8).

In light of the teachings of Masahiko, it would have been obvious to one of ordinary skill in the art to replace the lens disclosed by Henry with a Fresnel lens since Fresnel lenses are specifically adapted to focus light.

Claims **40-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Henry in view of Sha et al. as applied to claims 19-21, 23, 25, 26 and 46, and further in view of Hijikata (US 3,932,132).

Neither Henry nor Sha et al. disclose an elongate portion.

Hijikata discloses an optical system adapted to detect particular analytes in a fluid. The system comprises a transparent reagent carrier 11 on which an absorptive

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reagent is disposed, a lamp 12a for projecting light onto the reagent, and a tubular light guide 12c that guides the light emitted by the lamp to the reagent carrier (see Fig. 2).

The light guide focuses all the light emitted by the lamp towards the reagent carrier.

In light of the teachings of Hijikata, it would have been obvious to one of ordinary skill in the art to provide the modified microcard of Henry with a light guide so that the light projected in to the wells of the microtiter stick is directed towards the wells.

Response to Arguments

Applicant's arguments with respect to the art rejections have been fully considered but they are not persuasive.

Applicants' reference to the restriction requirement dated April 14, 2006 is not pertinent to the applicability of the Henry and the Sha et al. references as 35 U.S.C. 103(a) references. A restriction cannot be used as the basis for whether two references can be used as 35 U.S.C. 103(a) references because the concept of restriction is unrelated to whether two references can be used as 35 U.S.C. 103(a) references.

Applicants' argument that the claimed invention comprising chambers is different from the capped sample wells disclosed by Henry and Sha et al. is not persuasive. The combination of Henry and Sha et al. results in an enclosure defined by the sample wells of Henry and the sample well caps of Sha et al. A chamber is merely an enclosure. The fact that there is an air gap between the sample and the lid does not negate the existence of a chamber.

Applicants' argument that the lens disclosed by Henry does not focus light into the sample and collect light emitted by the sample is not persuasive. Henry discloses that immunoassay measurements are made through the lenses and that the lenses focus light (see lines 1-23, col. 8 Fig. 14). Although Henry does not explicitly disclose that the lenses "collect light emitted by the sample", it is inherent that it collects light emitted by the sample. An immunoassay measurements could not be attained if the lenses did not collect light emitted by the sample in the sample wells.

Applicants' argument that there is no motivation for combining the two references is also not persuasive. The Sha et al. reference was relied upon for its disclosure of the sample well caps, not the sample wells. Therefore, Applicants' reference to the intended use of the sample wells disclosed by Sha et al. is not pertinent. The purpose of the sample well caps disclosed by Sha et al. is to close the sample wells (see [0023]). Because the sample wells disclosed by Henry is open and susceptible to contamination, there is sufficient motivation for providing the sample wells with the sample wells caps disclosed by Sha et al.

Applicants' argument that there is no motivation for applying the teachings of the Ohta et al. reference is not persuasive. Examiner agrees with Applicants that the introduction of a convex lens would change the shape of the sample wells disclosed by Henry. However, Applicants failed to explain why the change in the shape of the sample wells would not allow the sample wells to perform their intended function. It appears that the alleged change in the shape of the wells would not affect the intended function of the sample wells.

Applicants' argument that there is no motivation for applying the teachings of the Warhurst et al. reference is not persuasive. Examiner agrees with Applicants that the opaque cover disclosed by Warhurst et al. would prevent optical reading of the sample stored in the sample wells. However, as indicated in the Office action, the cover can be used to prevent contamination while the sample wells are stored on the shelf. The Henry reference does not require a cover while the contents of the sample wells are assayed.

Applicants' argument that there is no motivation for applying the teachings of the Masahiko reference is not persuasive. Examiner agrees with Applicants that the same Fresnel lens disclosed by Masahiko cannot be incorporated into the sample wells disclosed by Henry. However, the Masahiko reference was relied upon for its disclosure of the properties of a Fresnel lens, not the actual lens. Figure 1 of Masahiko shows that Fresnel lens 6 focuses light in a direction perpendicular to its face no matter what angle the light hits the surface. In light of the disclosure, it would have been obvious to one of ordinary skill in the art to substitute the concave lens disclosed by Henry with a Fresnel lens for the focusing abilities of a Fresnel lens.

Applicants' argument that there is no motivation for applying the teachings of the Hijikata reference is not persuasive. Examiner disagrees with Applicants that the introduction of a light guide would change the shape of the sample wells disclosed by Henry. The light guide would be incorporated to the bottom exterior of the sample wells such that the light emitted by the external light 37 source would be guided toward the lens 26' of the sample wells (see Fig. 14). Even if the introduction of a light guide did

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change the shape of the sample wells disclosed by Henry, Applicants failed to explain why the change in the shape of the sample wells would not allow the sample wells to perform their intended function. It appears that the alleged change in the shape of the wells would not affect the intended function of the sample wells.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
11/06/06


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